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October 10 2007 5 OCT 24 A9:42

Acting Commissioner Andrew C. von Eschenbach
Food and Drug Administration
Division of Dockets Management
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 2005N-0345/RIN 0919-AF72

Dear Acting Commissioner von Eschenbach,

Please accept these comments on behalf of Planned Parenthood of Connecticut, in response to the FDA's request for public comment on whether to initiate a rulemaking process regarding the issues the Agency claims are raised by the application to make the emergency contraception drug Plan B available over the counter. Apart from the fact that this decision is long overdue, we join many in asserting that the remanding of this decision to the rulemaking process is just another in a long series of undue delays. We recommend that rulemaking not be initiated, and, instead, that Plan B be approved for over-the-counter use for women of all ages as soon as possible.

Here at Planned Parenthood of Connecticut, we filled nearly 19,000 prescriptions for Plan B last year. If even one quarter of those cases would have resulted in unintended pregnancies, we have likely averted 4750 unplanned births or abortions in a single state in a single year. All abortion rhetoric aside, is this not a desirable outcome? We strongly believe that it is. We know from firsthand experience the panic of women after unprotected sex, and their intense desire to act quickly to prevent pregnancy. Making Plan B available without prescription means that the difficulty of locating a willing provider or prescriber over a weekend or holiday period is no longer a concern. We all know that the sooner EC is ingested, the more effective it is.

The literature regarding reproductive behavior where Emergency Contraception is easily available is very clear. There is no decrease in the use of effective contraception and there is no indication that EC encourages increased sexual behavior. Rather it provides a safety net when contraception fails and when for a variety of reasons, effective contraception is not used.

As Acting Commissioner, surely you are aware that the resignations of reputable scientists like Dr. Susan Wood and Dr. Frank Davidoff from your agency and its advisory panel are indications that the FDA is on dangerous ground in terms of both the confidence of the science/research community and the public trust. We urge you to move to restore confidence in the FDA and approve the Plan B OTC application for women of all ages.

Sincerely,

Lester Silberman MD

Lester Silberman, MD, Medical Director

2005N-0345

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